VEER NARMAD SOUTH GUJARAT UNIVERSITY, SURAT.

M.Pharm.

Part I

100 MODERN ANALYTICAL TECHNIQUES (Compulsory Subject)
THEORY

1. Basic principle, applications and recent trends in chromatography.
    a. GC
    b. HPLC
    c. HPTLC
    d. Ion exchange chromatography
    e. Ion pair chromatography
    f. Size exclusion chromatography
    g. Affinity chromatography
    h. Electro kinetic chromatography
2. Theory of UV, IR, Derivative spectroscopy. FTIR, NIR, ATR and their applications in structural elucidation.
3. Theory and instrumentation of NMR, Pulse NMR and CM,. their application in structural elucidation
4. Basic principle and application of mass spectrometry.
5. Radio and Enzyme immunoassay, Quality control of radio pharmaceuticals.
6. Atomic Spectrometry.
7. Thermal method of analysis.
8. Basic principles, classification, instrumentation and application of LASER.
9. Reference standards-source, preparation, characterization, usage, storage and records.
10. Electrophoresis.
11. Water determination.
12. General principle, instrumentation and application of optical rotatory dispersion (ORD) and circular dichroism.

100 MODERN ANALYTICAL TECHNIQUE (Compulsory Subject)
PRACTICAL

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

REFERENCES

1. Munson Janues W. “Pharmaceutical Analysis” Marcel Dekker.
2. Willard “Instrumental Method of Analysis” CBS publication
3. Skoog “Principles of Instrumental Analysis”- Thomson.
4. Kenneth A. Conors “A textbook of Pharmaceutical Analysis, - John Wiley & sons.
5. Robert M. Silverstein, “Spectrometric identification of organic compound”
6. B.K.Sharma Instrumental methods of chemical analysis, Goel Publication, 23rd edition.

VEER NARMAD SOUTH GUJARAT UNIVERSITY, SURAT.

M.Pharm.

Part I

200 ADVANCES IN PHARMACEUTICAL SCIENCES (Compulsory Subject) THEORY

1. Pharmacokinetic approach to New Drug Discovery.
2. Basic concepts and Definition, Importance of ADME parameters in disposition therapeutics and development - their implications in drug discovery.
3. Overview on Computer Aided Drug Design (CADD) including QSAR, QSPR, Combinatorial Chemistry, High Throughput Screening (HTS)
4. Molecular Basis of Drug Action
5. Drug Latentiation
6. Basic concept, Prodrugs- functional groups, Bioprecurssor prodrugs Chemical Delivery System.
7. Biotechnology in Drug Discovery:
8. Cloning of DNA, Expression of cloned DNA, Manipulation of DNA sequence information, New Biological Targets for Drug Development, Novel Drug Screening Strategies, Novel Biological Agents, Antibodies, Antisense oligonucleotide Therapy, Gene Therapy
9. Herbal Neutraceutical as a new source for medicines
10. Study of Advanced Drugs From Natural Sources of following groups:
11. Anticancer, AntiAIDS, Hepatoprotectives, Antidiabetics, Antiarthritic, Adoptogenic, Cardiotonics, Antipyretics, Antimalarials, diuretics, Hypnotics, Braintonics, Urolithiatics, Antifilarial, Antihyperlipidamics,
12. Recent trends in the study of authentic and controversial drugs of above mentioned groups
13. Modern Photochemical Screening Techniques and Evaluation of Herbal drugs, their extracts and formulations- Concept of reverse Pharmacognosy
14. Natural Insecticides and Pesticides.
15. General animal models for screening of drugs. Ethics and techniques in animal handling & sampling protocols.

References

1. Wilson and Giswold's -Textbook of Organic Medicinal and Pharmaceutical Chemistry , Ed.Jaime N Delgado and W.A. Remers, Lippincott-Raven Inc NewYork.
2. Burger's Medicinal Chemistry and Drug Discovery, Ed.Manfred E. Wolff, John Wiley Sons Inc. New York.
3. Comprehensive Medicinal Chemistry, Vol-4, Ed. C. Hansch, Pergamon press. New York
4. Comprehensive Biotechnology, Ed. Murray Moo-Young, Pergamon press, New York.
5. National Center for Biotechnology information publications (www.ncbi.nlm.nih.gov)
6. Dewick Paul M. "Medicinal Natural Products-A Biosynthetic Approach"
7. Chakravarty T. K. "Herbal Options".
8. Progress in Controlled & Novel Drug Delivery Systems by N.K.Jain, CBS Publisher, New Delhi.
9. Drug Discovery & Evaluation by H.Gerhard Vogel.
10. Pharmacokinetics by Milo Gibaldi, Marcel Dekker Inc.

11. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
12. The practical evaluation of Phytopharmaceuticals by Brain and Turner.
13. Computer added drug design by T.J.Perun & C.L.Propst, Maarcel Dekker Inc.
14. Novel Drug Delivery Systems by Y.W.Chien, Marcel Dekker Inc.

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M.Pharm.

Part I

400 PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY
Specialization Paper – I

411 Pharmaceutical Formulation Development & Biopharmaceutics (Theory)

1. **Preformulation Studies**
   a. Physical, chemical and Pharmaceutical factors influencing formulation.
   b. Solid-state characterization: Crystallinity, hygroscopicity, Particle size and particle size distribution, compaction properties and etc.,
   c. Crystalline and polymorphism and its evaluation. Rational for selecting the preferred polymorph/crystalline form.
   d. General Principal and applications of Differential thermal analysis, Differential scanning colorimetery, X- Ray Diffraction, FT-IR in preformulation study.
   e. Drug-expient compatibility study.
   f. Traces of organic volatile impurities (OVIs) and their regulatory limits (residual solvents)
2. **Solubilization and solubilized system**
   a. Theoretical aspects and applications.
   b. Techniques for improvement in drug solubilization for development of various dosage forms.
3. **Dissolution study**
   a. Importance, objectives, equipments,
   b. Biological classification system (BCS); its significance on dissolution study and application in dosage form development.
   c. Selection of dissolution medium and conditions,
   d. Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent method.
4. **Stability study**
   a. Basic concept and objectives of stability study,
   b. Order of reaction and their application in predicting shelf life and half-life of pharmaceutical formulations,
   c. Importance of accelerated stability study,
   d. Effect of various environmental/processing factors (i.e. light, pH, metal etc.,) on stability of the formulation and techniques for stabilization of products against the same,
   e. Regulatory requirement related to stability testing with emphasis on matrixing/bracketing technique, climatic zone, impurities in stability study, photo stability testing etc.,
   f. Application of micricalorimetry in stability study
5. **Drug Absorption**
   Factor affecting drug absorption; i.e. physicochemical, physiological and pharmaceutical.
   Method of studying bioavailability and bioequivalence.
   Transport across CACO 2 monolayers-Biological, Pharmaceutical and Analytical considerations.

6. **Pharmacokinetic parameters**
    a. Basic concept and importance of biological half-life, volume of distribution, renal clearance, total body clearance, plasma protein binding, and absorption rate constant, elimination rate constant.
    b. Analysis of blood and urine data. Compartment models, kinetics of one and two compartment model.
7. **In-vitro In vivo Correlation (IVIVC)**
    c. Method of establishing IVIVC
    d. Factor effecting IVIVC
8. **Cosmetic and dental products**
    Formulation and evaluation of various cosmetic and dental products.

Reference:

1. Pharmaceutics “The Science of Dosage form design” by Aulton.
2. Encyclopedia of Pharmaceutical technology-volume: 1 to 19.
3. Remingtons “Pharmaceutical Sciences”
4. Lachman “The theory and Practice of industrial Pharmacy”
5. Pharmaceutical dispensing by Husa.
6. Drug stability (Principles and Practices) by Jens. T. Carstensen.
7. Stability of drug and dosage forms by Yoskioka.
8. Pharmaceutical dissolution testing by Banaker.
9. United States Pharmacopoeia.
10. Applied Biopharmaceutics and pharmacokinetics, by Leon Shargel,
11. Pharmacokinetic by Welling and Tse.
12. Pharmacokinetics by Gibaldi and Perrier.
13. Modern pharmaceutics by G.S.Banker.
14. Clinical pharmacokinetics, concepts and application by Rowland and Tozer.
15. Biopharmaceutics and pharmacokinetics-An introduction by Notari.
16. Pharmacokinetics for pharmaceutical scientist by John Wagner.
17. Techniques of Solubilization of Drug by Yalkowsky.
18. Novel Cosmetic Drug Delivery System by Magdassi and Touitou.
19. Cosmetics by Sagarin.
20. Perfumes, Cosmetics and Soaps by Poucher.
21. Dissolution, Bioavailability and Bioequivalence by Abdul**.**

PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY Specialization
Paper-I
Practicals

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

VEER NARMAD SOUTH GUJARAT UNIVERSITY, SURAT.

M.Pharm.

Part I

400 PHARMACEUTICS and PHARMACEUTICAL TECHNOLOGY Specialization
Paper-II

412 Industrial Pharmacy
(Theory only)

1. Preparation of Qualitative and quantitative departmental lay out with equipments required for different dosage forms-solids, liquids, semi solids, sterile.
2. Detailed study of the equipments required in the manufacture of different dosage forms as per schedule-M.
3. Pharmaceutical factory location: Selection, layout and planning, utility service-service facilities and personnel facilities.
4. Pilot plants, scale up techniques.
5. GMP and its application.
6. Production planning and controls.
7. Preparation of documents like batch manufacturing record, batch packing record, validation protocols,
8. Preparation of standard operative procedure (SOPs) for equipments, manufacturing or processing steps.

Reference:

1. Lachman “The theory and Practice of industrial Pharmacy” 3rd edition.
2. Remingtons “Pharmaceutical Sciences”.
3. Bentley’s Pharmaceutics.
4. Pilot plants model and scale-up methods, by Johnstone and Thring.
5. GMP practices for pharmaceutical-James Swarbrick.
6. How to practice GMPs by P.P.Sharma.
7. Chemical engineering plant design by Vibrant.
8. Pharmaceutical process validation by Loftus and Nash.
9. Drug and cosmetic act 1940.

VEER NARMAD SOUTH GUJARAT UNIVERSITY, SURAT.

M.Pharm.

Part I

500 PHARMACEUTICAL CHEMISTRY SPECIALIZATION
Paper-I 511 Advanced Organic Chemistry-theory

1. Chemical Bonding and Structure.
2. Chemical bonding, Bond energies, Orbital theory, Orbital Hybridization, Resonance, Electronegetivity, Polarity, Hyperconjugation.
3. Chemical Reactivity and Molecular Structure.
4. Kinetics, Resonance, Steric, inductive and electrostatic effect on reactivity, acids and bases.
5. Various Reaction mechanisms
    a. Substitution Reaction: Nucleophilic substitution reaction in aliphatic systems- S_N1, S_N2. S, Hydride transfer reaction, Cram's rule, Participation of neighboring group in nucleophilic substitution-reactions and rearrangements. Aromaticity, electrophilic and nucleophilic substitution in aromatic systems, Reactivity and orientation in electrophilic substitution.
    b. Elimination Reaction: Beta elimination reactions, E1,E2, & E1cb,Mechanisms, Hoffman and Saytzeff's elimination.
    c. Addition Reactions: Nucleophilic additions, Markonikov's rule.
    d. Rearrangement reactions: Transannular rearrangements, Pinacol and related rearrangements, Beckman rearrangements, Hoffman rearrangements.
    e. Free radical reactions: Formation – Detection – Reactions, Homolysis and free radical displacements – additions and rearrangements of free radicals.
6. Reactions of carboxylic acids and esters,BAC2, AAc2, BAL2, BAL1, AAL1. Claisen condensation , decarboxylation, carbanions, enolisation, keto-enol equilibria.
7. Stereochemistry, Molecular asymmetry, compounds with one, two or more unequal asymmetric carbon atoms, racemic modifications, Configurations-absolute, relative, synthesis of optically active compounds-cyclohexane, six membered heterocyclic rings-stereoisomerism of compounds with asymmetric plane – allenes and related compounds – stereoselective synthesis.
8. Study of individual reactions-allylic rearrangement-Amdt Eister synthesis, Baeyer-Villiger reaction-Baker-venkatraman reaction-benzidine rearrangement-benzilic acid rearrangement-Buchner method of ring enlargement-Carrol reaction - Curtius rearrangement-Dimorth rearrangement-Fries rearrangement- Lossen Schmidt rearrangement-Pinner reaction-Reformatsky reaction-Robinson-Annelation reaction-Witting reaction-Diels-Alder reaction.
9. Use of diazonium salt-diazomethane and peracids in sysnthesis.
10. Y-lides of phosphorus-sulphur-nitrogen
11. Photochemistry: Theory-energy transfer-characteristics of photoreactios- typical photo reactions.
12. Concerted pericyclic reactions – electrocyclic reactions – sigmatropic rearrangements-cycloaddition reaction

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M.Pharm.

Part I

500 PHARMACEUTICAL CHEMISTRY SPECIALIZATION Paper-I (Practical) (Advanced Organic Chemistry)

Laboratory examination including oral and practical examination in general course illustrative of theoretical section in the syllabus.

REFERENCES:

1. Gould-Mechanism and structure in Organic Chemistry.
2. Sykes- A Guidebook to Mechanism in Organic Chemistry.
3. March- Advanced Organic Chemistry Reaction Mechanism and Structure.
4. Eliel- Stereochemistry of Carbon Compounds.
5. Alexander- Principles of Ionic Organic Reactions.
6. Surrey- Reactions in Organic Chemistry
7. Hendrickson- Organic Chemistry
8. Carey F.A.- Advanced Organic Chemistry Part-A.

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M.Pharm.

Part I

500 PHARMACEUTICAL CHEMISTRY SPECIALIZATION Paper-II (Theory only)

512 Chemistry of Natural Products

1. Carbohydrates: Disaccharides – determination of structures – sucrose-maltose-lactode-polysachharides-cellulose-starch-introduction to lignin-pectin-peptic substances.
2. Amino acids & polypeptides: Introduction-classification-synthesis of amino acids-poly peptides synthesis.
3. Synthesis of naturally occurring proteins-structure of polypeptides –amino and Carboxyl end degradation-protein classification-composition-structure-chemistry of oxytocin-insulin-andiotensin-peptides of medicinal importance.
4. Alkaloids: General methods of degradation and structure determination-study of constituents of atropine-Introduction-general nature-synthesis-structure of anthocyanidin-flavones-isoflavons-depsides.
5. Purines and nucleic acids.
6. Heterocyclic chemistry ; Introduction-nomenclature-properties-synthesis and reactions involved in five member and six member heterocyclic. Heterocyclic with one,two of more hetero atoms, biological importance of heterocyclics.

REFERENCES:

1. Finar – Organic Chemistry Vol 1 & 2.
2. Fieser and Fieser – Steroids
3. Gilman – Organic chemistry.
4. Fleming – Selected Organic synthesis.
5. Nakanishi – Natural Product Chemistry – Vol 1 and 2.
6. Palmer – Structure and Reaction of Heterocyclic Compounds.
7. Acheson – Introduction to Chemistry of Heterocyclic Compounds.

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M.Pharm.

Part I

600 Pharmacology Specialization Paper-I Theory

611 Advanced Systemic Pharmacology

Pharmacology of the following

1. Parasympathomimetics
2. Parasympathetic blocking agents
3. Sympathomimetics
4. Sympathetic blocking agents
5. Ganglion stimulants & blockers
6. Neuromuscular stimulants & blockers
7. General & local Anaesthetics
8. Sedatives & Hypnotics
9. Antiepileptic
10. Psychopharmacological agents
11. Analgesics
12. Anti-inflammatory agents
13. Drugs used in Alzeimer's disease
14. Drugs used in Migraine
15. Antiparkinson's drugs
16. CNS stimulants
17. Cardiotonics
18. Antihypertensive drugs
19. Antiarrhythmic drugs
20. Drugs used in Ischaemic heart disease
21. Drugs used in Atherosclerosis
22. Diuretics
23. Drugs used in Gastro intestinal disorders
24. Drugs used in Respiratory disorder
25. Drugs used in Urino-Genital disorders
26. Drugs used in Endocrine disorders

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M.Pharm.

Part I

600 Pharmacology Specialization Paper-I Practical

(611 Advanced Systemic Pharmacology)

1. Calculation of PA_2, PD_2, PD'_2, values using isolated tissue.
2. Preparations – Rat Fundus strip, Rat Uterus, Guinea pig Tracheal chain, Rabbit Aortic strip, Ileum preparations, Mammalian heart etc.
3. Simple Bioavailability studies
4. Bioassays of Autonomic drugs & Autacoids
5. Exercises in Molecular Pharmacology

References:

1. Pharmacokinetics by: Milo Gibaldi & Donald Perrier
2. Biopharmaceutics & Pharmacokinetics, An introduction by E. Notary
3. Drug metabolism by Berhard Testa & Peter Jenner
4. Principles of drug action by Goldstein, Aranow & Kalman
5. International & National Journal

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M.Pharm.

Part I

600 Pharmacology Specialization Paper-II (Theory)

612 Cellular & Molecular Pharmacology

1. Molecular structure of Biological membrane & transport mechanism across cell membrane
2. Factors influencing drug absorption
3. Drug distribution- Protein binding, Tissue binding- Blood Brain Barrier, Placental barrier, Volume of distribution
4. Biotransformation of drugs- Microsomal, Non microsomal metabolism, Factors influencing, Enzyme induction & inhibition, Pharmacogenetics
5. Drug excretion- Renal & Non renal, Factors influencing Renal clearance, Biological half life
6. Pharmacokinetics- Single & multiple dose therapy, Single & multiple compartment models, Bioavalibility
7. Theories of drug receptors & drug receptor interactions
8. Drug antagonism
9. Cellular molecular basis of drug action
10. Neurotransmitters & Neuropeptides in CNS disorders
11. Electro physiology of heart- Pathophysiology of cardiac disorders
12. Molecular structure & Functions of ion channels
13. Physiology of renal functions- Electrolyte metabolism, Acid base equilibrium, Renin Angiotensin system
14. Vitamins
15. Haematinics
16. Gene expression & Regulation, Gene Cloning & Pharmacogenetics.
17. Autacoids
18. Immnopharmacology

References :

1. Clinical Pharmacology By D.R Lawrence & P.N Bennett
2. Pharmacology & Pharmacotherapeutics By R.S Satoskar & S.D Bhandarkar
3. The Pharmacology Basis Of Therapeutics, 10th Edition By Louis S Goodman & Alfred Gillman
4. Pharmacology By H.P. Rang & M.M.Dale

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M.Pharm.

Part I

700 PHARMACOGNOSY SPECIALIZATION PAPER-I (Theory)

711 Chemistry of Medicinal Natural Products

1. Classification of medicinally active constitutes general methods of isolation, purification and production of natural products: Alkaloids, Glycosides, Tannins, Volatile oils. Fixed oils, Steroids.
2. General chemical tests to identify them and their quantitative determination.
3. Study of different biogenetic pathways of therapeutically important active constitutes.
4. Study of sources, isolation, estimation, biosynthesis, structure elucidation, stereochemistry, therapeutic and economic importance of following pharmaceuticals:
   a. Atropine, colchicines, Ergometrine, Vincristrine, Camptothecin.
   b. Diosgenin, Sennosides, Glycyrhetinic acid, Guggul lipid, Rutin, Psoralen, Xanthotoxin, Digoxin
   c. Menthol, Thymol, Citral, Taxol
   d. Podophyllotoxin
   e. Penicillin, Streptomycin, Griseofulvin
   f. Echimic acid, Ginkolide, Silymarin, Picroside, Artemisin, Gymnemic acid

VEER NARMAD SOUTH GUJARAT UNIVERSITY, SURAT.

M.Pharm.

Part I

700 PHARMACOGNOSY SPECIALIZATION PAPER-I
(Practical)

711 Chemistry of Medicinal Natural Products

Laboratory examination including oral and practical examination in general course illustrative of theory section in syllabus

References:

1. Manske- The Alkaloid-Chemistry and physiology
2. Sim- Medicinal plant Glycosides.
3. Sim- Medicinal plant Alkaloids
4. IUPAC- Chemistry of Natural products-International symposium
5. Zechmeister-Progress in the chemistry of Organic natural products
6. Reinhold- Liwschitz- Progress in phytochemistry
7. Wagner-Wolf- New natural products and plant Drugs with Pharmacological, Biological or Therapeutic activity
8. Finar- Organic chemistry
9. Peach-tracey- Modern methods of Plant Analysis
10. Geissman- Modern methods of Plant Analysis
11. Garatt- The Quantitative Analysis of Drugs
12. Backett-Stenlake- Practical Pharmaceutical chemistry
13. Arthur- Symposium on Phytochemistry
14. Pridham- Swain- Biosynthetic pathways in higher Plants
15. Greenbury- Metabolic pathways
16. Margaret-Brain- Secondary Plant Metabolism
17. Wagner-Horhammer- Pharmacognosy and phytochemistry
18. Harborne- Comparative Biochemistry of Flavonoids
19. Lehninger- Principles of Biochemistry
20. Bonner- Plant Biochemistry
21. Harborne- Phytochemical methods
22. Rosenthaler- The chemical investigation of the plants
23. Cheronis- Organic function group analysis
24. Nakanishi- Natural product chemistry, Vol.I & Vol.II

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M.Pharm.

Part I

700 PHARMACOGNOSY SPECIALIZATION PAPER-II (Theory only)

712 Biotechnology and cultivation of medicinal plants

1. Medicinal plants biotechnology
2. Principles of plant genetics, genetic factors affecting plants and their constituents.
3. Plant growth regulators and factors affecting cultivation of the medicinal plants
4. Production of medicinal plants as raw materials and importance of Ergot, Ispaghula, Senna, Digitalis, Glycyrrhiza, Dioscorea, Mentha, Cardamom, Cinnamon, Aloe, Sandalwood, Pinus, Ginger, Shatavari, Musli, Taxus Baccata, Ginseng, Majith, Guggul, Artemisia

References:

1. Ramstad- Modern Pharmacognosy
2. Herskowitz- Principles of genetics
3. Stricknerger- Genetics
4. Hess- Plant physiology
5. William- Genetical principles and plant breeding
6. Kruse- Patterson- Tissue culture- Methods and applications
7. Bartz- Reinhard- Zenk- Plant tissue culture and its biotechnical applications
8. John- Dodds- Lorin- Experiments in plant tissue culture
9. Handa S.S and Kaul, K.L.- Suppliment to cultivation and utilization of medicinal plants
10. Gamborg, O.L. an Wetter, L.R.- Plant tissue culture methods, National research council of Canada, Saskatchewan
11. H.E.Street- Plant tissue and cell culture, Blackwell Scientific publication
12. P.Prave, U. Faust, W. sttig and D.A. Sukatsch, Fundamentals of Biotechnology, V.C.H. Publishers
13. Alan T. Bull, Howarb Dalton, and Murray Mao- Young – Comprehensive biotechnology, " The principles, application and regulation of biotechnology in industry, agriculture and medicine" Vol. 1 to 4
14. Pruthi J.S.- Major species of India
15. CSIR – Cultivation and utilization of medicinal plants
16. CSIR- Wealth of India, raw materials

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M.Pharm.

Part I

800 Quality Assurance Specialization Paper I
Theory

811 Pharmaceutical Quality Assurance- Biological Evaluations, Clinical Research and NDA

1. Calibration of Equipment & Instruments
2. Analytical Method Development & its Validation
3. Development of Monograph
4. Biological Standardization: General Principles, Scope & limitations of Bioassays. Bio- assays of some Official Drugs
5. Sterility Tests: Methodology & Interpretation
6. Pyrogens: Production, Chemistry Properties of Bacterial Pyrogens & endotoxins, official Pyrogen tests
7. Preclinical Drug Evaluation, acute, sub acute & Chronic toxicity studies, LD_{50} & ED_{50} determination, evaluation of compound for its biological activity, study of special toxicities like teratogenicity & mutagenicity.
8. Drug Stability: Solution stability, solid stability, parameters for physical stability testing programme, accelerated stability studies shelf assignment.
9. Approval of New drugs: Investigational New Drug (IND) submission, format & content of IND, content of Investigator Brochure, general consideration of New Drug Approval (NDA), specific requirements, content & format of NDA, manufacturing control requirement of NDA.
10. Clinical Research—Clinical Research Protocols, objective & protocol design, Helsinki declaration, US-FDA & ICH guideline for Clinical trials for drugs & dosage forms, reviews & approval of Clinical Study, Good Clinical Practices.
11. Pharmacokinetic & Bioequivalence study. Requirement criteria for Bioequivalence study.

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M.Pharm.

Part I

Quality Assurance Specialization Paper I
Practical
811 Pharmaceutical Quality Assurance- Biological Evaluation, Clinical Research and NDA

Laboratory Examination including oral & practical examination in general course illustrative of theory section in syllabus.

BOOKS RECOMENDED

1. Indian Pharmacopoeia
2. British Pharmacopoeia
3. U.S. Pharmacopoeia
4. Enzymes – Biochemistry, Biotechnology, Clinical Chemistry
5. Michael E. Swartz, Analytical method development & validation.
6. S.Suzanne Nielsen, “Introduction to the Chemical analysis of foods”.
7. D.C.Garratt “The quantitative analysis of drugs” 2nd edition.

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M.Pharm.

Part I

800 Quality Assurance Specialization Paper II (Theory only)

812 Pharmaceutical Quality Assurances- QA, GMP, GLP

1. Concepts of Philosophy of QA, GMP, GLP
2. Good Manufacturing Practices:
   a. Organization & Personnel, responsibilities, training, hygiene.
   b. Premises: Location, design, Plant Layout, Construction, Maintenance & Sanitation, Environmental control, utilities & services like gas, water, maintenance of sterile areas, and control of contamination.
   c. Equipments: Selection, purchase specifications, maintenance, clean in place, sterilize in place, Methods (TP & STP)
   d. Raw Materials: Purchase specifications, maintenance of Stores, selection of Vendors, control on raw materials & finished dosage forms.
   e. Manufacture of & control on dosage forms: manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes & facilities.
   f. In Process quality controls on various dosage forms: Sterile & non sterile , standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc
   g. Packaging & labeling control, Line clearance, reconciliation of labels, cartons & other packaging materials.
   h. Quality control Laboratory: Responsibilities. Routine controls instruments, reagents, sampling plans, standard test Procedures, protocols, data generation & storage, quality control documents, retention samples, records, audits of quality control facilities.
   i. Finished product release, quality review, quality audits and batch release documents.
   j. Warehousing, design, construction, maintenance & sanitation; good warehousing practice, materials & management.
   k. Distribution & distribution records, handling of returned goods, recovered materials & reprocessing.
   l. Complaints & recalls, evaluation of complaints, recall procedures, related records & documents.
   m. Waste disposal, scrap disposal procedures & records.
3. Good Laboratory Practices.
4. Quality Assurance Standards.
5. WHO certification.
6. Testing of Packaging materials.
7. Quality Audit.
8. Specifications for materials, intermediates & finished product.

References:

1. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics: Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.
5. P.P.Sharma “How to practice GMPs”, 3rd edition Vandana Publi.
6. P.P.Sharma “How to practice GLP” Vandana Publi.